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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/536,810 | 09/19/2006 | David L. Kaplan | 5363-3259 | 4571 |
| 21125 7590 04/27/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | EXAMINER MACAULEY, SHERIDAN R | |
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| | | | 1609 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 31 DAYS | | 04/27/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/536,810

Applicant(s)

KAPLAN ET AL.

Examiner

Sheridan R. MacAuley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-169 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 119-169 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 119-137, drawn to a method for enzymatically synthesizing a functionalized polymer. *Note that election of this group will also require an election of species of monomers, antioxidants, forms, and types of polymers. See species election requirement below.*

Group II, claim(s) 138-146, drawn to a method of protecting oxygen sensitive material from degradation.

Group III, claim(s) 147-152, drawn to a medical device. *Note that election of this group will also require an election of species of device types. See species election requirement below.*

Group IV, claim(s) 153, drawn to an antioxidant coupled packing material.

Group V, claim(s) 154 and 155, drawn to a delivery system for antioxidants.

Group VI, claim(s) 156-165, drawn to a method of controlled delivery of antioxidant to a subject. *Note that election of this group will also require an election of species of forms. See species election requirement below.*

Group VII, claim(s) 166-169, drawn to an ascorbyl coupled polymer. *Note that election of this group will also require an election of species of Y-, Z- and R-groups. See species election requirement below.*

2. The inventions listed as Groups I through VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature common to Groups I through VII is a polymer comprising antioxidant

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coupled monomers. However, Willette et al. (US Pat. 4,096,319) teach a polymer comprising antioxidant coupled monomers (col. 3, lines 31-63). Therefore, the inventions of Groups I through VII do not share a special technical feature that makes a contribution over the prior art.

Species Election Requirement

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. If applicant elects Group I, election is required of the various monomers recited in claims 123 and 135. For example, applicant may elect lactones (recited in claim 123), nucleosides (recited in claim 123), polyesters (recited in claim 135), or a specific combination of the monomers recited in claim 123 or claim 135.
- B. If applicant elects Group I, election is required of the various antioxidants recited in claim 129. For example, applicant may elect ascorbic acids, thioethers or flavones.
- C. If applicant elects Group I, election is required of the various forms recited in claim 133. For example, applicant may elect films, fibers or a specific combination of the form recited in claim 133.
- D. If applicant elects Group I, election is required of the types of polymers recited in claims 136 and 137. Applicant may elect either a homopolymer (recited in claim 136) or a copolymer (recited in claim 137).

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- E. If applicant elects Group III, election is required of the types of medical devices recited in claim 148. For example, applicant may elect either stents, catheters or sutures.
- F. If applicant elects Group VI, election is required of the various forms recited in claim 162. For example applicant may elect a film, a fiber, or a specific combination of the forms recited in claim 162.
- G. If applicant elects Group VII, election is required of the various Y-groups recited in claim 166. Applicant may elect that Y is absent, C_2H_2O , C_7H_4O , or a linking group.
- H. If applicant elects Group VII, election is required of the various Z-groups recited in claim 166. For example, applicant may elect O, S, N, C_6H_3 or C_aH_b .
- I. If applicant elects Group VII, election is required of the various R-groups recited in claim 166. For example, applicant may elect that R is absent, an oxygen, an alkyl or a halide.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

If applicant elects Group I, election is required of a species from each of species groups A-D. If applicant elects Group III, election is required of a species from species group E. If applicant elects Group VI, election is required of a species from species group F. If applicant elects Group VII, election is required of a species from each of species groups G-I.

The following claim(s) are generic: Claim 119 is generic for species groups A-D. Claim 147 is generic for species group E. Claim 156 is generic for species group F. Claim 166 is generic for species groups G-I.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The technical feature common to Groups I through VII is a polymer comprising antioxidant coupled monomers. However, Willette et al. (US Pat. 4,096,319) teach a polymer comprising antioxidant coupled monomers (col. 3, lines 31-63). Therefore, the inventions of Groups I through VII do not share a special technical feature that makes a contribution over the prior art.

6. Inventions of species groups A through I are directed to related products and processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions have materially different functions and effects. For example, the use of different monomers or antioxidants would result in a materially different polymer, as would the use of a single type of monomer or a plurality of different monomers; the production of a film would have a materially different effect from the production of a fiber; the production of a stent would have a materially different effect from the production of a catheter; and the use of different Y-, Z- and R- groups would result in a materially different molecule, having distinct structural and physical characteristics. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM



MARY MOSHER
SUPERVISORY PATENT EXAMINER

4-25-07